Nova Scotia Fish Packers Association

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March 24, 2003

Mr. Robert Lake
Director, Office of Regulations and Policy
Center for Food Safety and Applied Nutrition
Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD, USA 20852

DOCKET NUMBER: 02N-0278
TITLE: Section 307, Bioterrorism Preparedness; Prior Notice of Imported Food Shipments

Dear Mr. Lake:

The Nova Scotia Fish Packers Association represents 65 seafood processing and exporting companies at various locations throughout the province. Our member companies export a variety of live, fresh, frozen, salted dried, canned and marinated seafood products to the USA. We estimate our members' exports to the USA in 2002 to have exceeded a value of $400 million Canadian.

Live lobster exports to American importers from Nova Scotia suppliers probably exceeded $300 million Canadian in 2002. Fresh fish and scallop shipments exceeded $100 million in value. Most of these shipments could be termed just-in-time deliveries to US buyers and distributors who supply their food service and retail customers with only the best quality, premium seafood.

The harvest of wild caught seafood is not increasing, but the price and customer expectations are increasing as seafood is seen as a special meat protein. From the boat to market, fresh or live seafood has to move quickly and under the best conditions if the industry is to meet our customers' demands. Fresh fish or scallops that have aged to the

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point where the fresh taste and scent have been replaced by something less appetising can no longer compete with steak on a restaurant menu.

Live lobster typically has a two-day shelf life once it has been removed from the water and begins its trip to the market. Lobster that has died en route to market has little, or no, market value.

The NSFPA member companies are particularly concerned about the impact of the draft Prior Notice Regulations put forward in the Federal Register on February 3, 2003 to implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. We would ask you to take the following into consideration in making amendments to the regulations prior to their finalisation:

When Must the Prior Notice Be Submitted to USFDA? The NSFPA urges the USFDA to amend this element of the rule to provide the needed commercial flexibility to our exporters to ensure the highest level of compliance for USFDA in allowing exporters to select one of two options that would accommodate our members' general business practices, and provide accurate information in advance to FDA. If necessary, FDA could require that, once selected, the option would be locked.

Option 1. Exporters whose business practices generally align with the current proposal (Prior notice to be provided by noon of the calendar day before the shipment reaches the border, with the ability to submit limited amendments for product identity and quantity) would elect to comply with FDA's existing proposal.

Option 2. Exporters that generally service quick turnaround orders (e.g. same day orders, perishable products, catch of the day, just-in-time deliveries) could elect to restructure commercial practices, if necessary, to ensure that all the required information is available and notified **no later than four hours before the shipment arrives at the border.** Under this option, no amendments would be permitted. This approach would better serve these types of transactions and provide accurate and full information to FDA earlier than the two hours provided for amended notices in the FDA's existing proposal. This would enable Canadian exporters to comply with FDA's need for accurate information sufficiently in advance to interdict perceived risks. In considering this approach, the FDA should consider that the vast majority of these types of transactions would be daily, repetitive shipments of low risk products from Canadian companies well known to FDA.

A significant portion of Nova Scotia's $800 million plus seafood exports to the USA in 2002 was transported by truck on the Digby, NS to St. John, NB ferry and then on to the Calais/St. Stephen border point. In the winter, the most used ferry crossing time leaves Digby, NS at 4:30 PM. Truck shipments on that ferry could be expected to reach Calais/St. Stephen by 8:00 PM. A $300,000 shipment of live lobsters (2-day shelf life out of water) will have to wait at least four hours at the border before the shipment is eligible for FDA inspection under the proposed rule. Lobster buyers in the Boston and New York areas typically want the shipment delivered before 6:00 AM. Since it is 7 - 8 hours from Calais, Maine to Boston, the lobster shipment can not arrive by 6:00 AM Boston time.

Shipments to New York City normally take about 12 hours of travel time from the Maine border and it would also be impossible to reach that market at the desired time under the proposed rule. The Fulton Fish Market in New York City is open and receiving shipments as early as 2:00 AM.

Many of our fresh seafood and lobster truck shipments contain product from multiple suppliers destined to different US customers at various locations. Typical drop off points might include Ellsworth and Portland, Maine; Gloucester, New Bedford, Boston, MA; and then on to New York. All destinations want the shipments to arrive before 6:00 AM so that early morning distributions to retail and restaurants can take place. Shipment arrivals later in the day are normally received at a lesser price.

Under the proposed rule, if a fresh fish or a live lobster shipment arrives at the border and the Prior Notice information contains errors, or did not meet the noon deadline, then the shipment will require a new submission and another 24 hours before FDA can process/inspect the shipment at the border. This scenario would likely result in the loss of the $300,000 truckload of lobsters. Such a loss could lead to the bankruptcy of a Nova Scotia exporter.

Under our 4 hour proposal, we could close the doors on our trucks, provide FDA with accurate information about the shipment, catch the ferry, be processed by FDA without a significant wait at the border and reach our New England delivery points in time for the early morning distribution. Under the four-hour option, a clerical error in the submission, or a late submission would allow for another submission and processing by FDA in another four hours rather than having to wait another 24 hours as required under the draft proposal. With a shipment of live lobsters, the reduced wait time while the resubmission is processed may be the difference between getting the shipment to market alive rather than dead.

During the summer months, when fresh fish and scallop shipments are at their height, the ferry leaves Digby for St. John, NB at 12:00 noon and at 7:45 PM. For just-in-time orders of fresh fish or scallops during the summer months, the proposed calendar day before... option would eliminate the option of using the 12:00 noon ferry. The 7:45 PM sailing works, but we still can't get our product to most markets before 6:00 AM because of the 12:01 AM FDA earliest inspection time at the border. The 12:01 AM problem also applies to truck shipments travelling to the Houlton, Maine border point overland, rather than using the Bay of Fundy ferry crossing. We will have the added cost of having to use two drivers on the overland route, and we still will not be able to get the shipment to Boston or New York at the desired time. It is clearly the view of NSFPA members that the 4-hour option that we are proposing will allow us the flexibility to meet our market time schedules without a significant negative impact.

Who Can Submit the Notice? The proposed rule, under section 1.285, would require the prior notice to be submitted by a purchaser or importer who resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United States, acting on behalf of the US purchaser or importer. With respect to the

unique commercial environment at the Canada-United States border, this proposal will cause serious adverse and unnecessary commercial consequences for NSFPA exporters and their U.S. customers. Most seafood imports from Canada at the land border are sold on the basis of the Canadian exporter taking responsibility for the entire U.S. Customs and FDA transaction at the border. The Canadian exporter is the actual owner of the product until delivered to the U.S. customer. The invoice price to the U.S. customer will normally be inclusive of all U.S. Customs, or other U.S. border agency charges. The Canadian seafood exporter normally hires and pays a U.S. Customs house broker to act as its agent at the border, including all liabilities for duties or fees, including, for example, any redelivery to FDA and U.S. Customs of any seafood shipments found to be non-compliant by FDA. It is the Canadian seafood exporter, for legal purposes, that is the U.S. importer of record.

The NSFPA requests that FDA should amend the rule to include Canadian seafood exporters, or their U.S. agents, in the requirements for who must submit the prior notice, any amendments or updates.

We note that the U.S. Congress did not specify which parties must submit the notice. These circumstances may be unique to the Canada/USA border and, if necessary, FDA should exercise the needed regulatory flexibility to provide specifically for these circumstances.

Since the draft regulations were published on February 3, 2003. NSFPA members who export to the USA have been contacting their American customers to survey the level of awareness of their responsibilities under the draft regulations. Almost all of those contacted had no awareness and were of the opinion that the responsibility for dealing with FDA and US Customs was, and should continue to be, the responsibility of their Canadian suppliers. Even if these importers were so inclined to assume the responsibility, NSFPA members feel that we will be taking an unacceptable financial risk if the administrative responsibility for filing the information correctly and on time falls to our American customers. Canadian live and fresh seafood shipments will likely be seen as a costly hassle, and to be avoided by some of our customers if an alternative is available.

The proposed rule requires the US importer, or his agent, to update FDA if a truck arrival time is postponed by more than 3 hours due to bad weather or a breakdown. In the wintertime, most of our seafood shipments are moving by truck toward the border at night after the normal work hours of our US customers. The current practice is for the driver, or dispatcher, to inform the Canadian exporter who owns the shipment of any significant delays. Again, NSFPA members feel that it makes sense to provide an option for the Canadian exporter, or his agent in the USA, to provide FDA with arrival time update information.

Under the proposed rule, where the shipment may be the subject of an inadequate notice, it is the Canadian exporter that normally owns the product at the border that would be held or sent to a secure facility. The FDA will, however, be requiring the resident U.S. customer who does not have a financial interest in the product to bear the responsibility

for complying or with disposal of the product. The inclination may be to simply abandon the shipment and cease to do business with the Canadian exporter.

From an operational standpoint, FDA is requiring detailed and extensive information for the prior notice. The level of detail is mostly consistent with the information normally submitted by U.S. Customs brokers acting as agents for importers of record. It is the Canadian seafood exporter that hires the U.S. Customs broker and that provides this information to the broker acting as the exporter's legal agent. The proposed rule would result in this information continuing to be submitted by Canadian seafood exporters and their U.S. Customs brokers for Customs purposes yet, at the same time, requiring for the same transaction, the submission of essentially the same data by a resident U.S. party (hiring the same or a different broker) solely to comply with the FDA prior notice requirement. This will inevitably introduce complications, delays and inaccuracies for the FDA.

The NSFPA suggests that it makes a great deal of sense for FDA to synchronise the definitions and input data elements with what is required by U.S. Customs. The intent should be to streamline the process and reduce the cost that business must bear.

Quantity Changes Before Arrival - The NSFPA would urge the FDA to amend section 1.294 to **allow for the update** of product quantities **prior to two hours of arrival time** at the border. We would suggest that for quantity changes a notice to update should not be required when the prior notice is submitted. Quantity should, thus, be added to port of entry and arrival time as changes that can be submitted as an update up to two hours before the arrival of the shipment at the border. This change will reduce the negative impact on fresh fish shipments where quantities are an estimate until the boat has landed and the intended customer knows how much is available.

Country of Origin - FDA, in the proposed regulation, defines the originating country for wild caught fish for purposes of originating in the United States as being harvested in the U.S., or by a U.S. flagged vessel, or processed by a U.S. flagged vessel. **Otherwise, the originating country is the country under which the harvesting vessel is flagged.** FDA should **amend this rule to define the country of origin as the country in which the fish were last processed.** We would like to see consistency in this definition with the interpretation in NAFTA and used by the WTO. U.S. Customs follows the NAFTA and WTO interpretation. Fish is a globally traded and sourced raw material which Canadian processors often source from several countries (sometimes processed with domestic fish) to make a like product for export.

Defining country of origin in a different way than required by U.S. Customs will lead to inevitable submission errors for prior notices. From a risk perspective, the last point of processing before exportation to the USA would likely be the point of greatest risk and of greatest interest to FDA.

Reduced Risk Information With Prior Notice - Seafood companies should have the means on the prior notice electronic form (also on the facility registration form) to

indicate that they have been accepted as a partner by U.S. Customs in the Customs Trade Partnership Against Terrorism program. Canadian seafood companies should also be able to indicate that they are registered with and inspected by the Canadian Food inspection Agency. FDA, in its analysis in the Federal Register, provided some potential impact scenarios if natural pathogens were to be deliberately introduced into food products. Salmonella, shigella and cyclospora were used in the examples. Registered Canadian seafood plants operate under a Canadian Food Inspection Agency Quality Management System that is HACCP based. Canadian processors, registered in the program, devote considerable resources to make sure that the risks from such pathogens are minimized.

Canadian Food Inspection Agency inspectors regularly monitor and audit the industry's compliance with our risk control system. Many Canadian seafood companies (NSFPA member companies have been in the Vanguard in working with U.S. Customs) have devoted considerable time and effort to developing company security plans and practical measures that will guard against the possibility of someone intentionally adulterating product with pathogens such as those mentioned in the analysis.

Companies that have been accepted as CTPAT partners by U.S. Customs have had their security programs reviewed by US Customs and have been accepted as low risk suppliers. Companies that are also registered with the Canadian Food Inspection Agency's QMP/HACCP program should add another level of risk reduction assurance. FDA could use such information, if it can be submitted in the prior notice, in focusing inspection efforts on the higher bioterrorism risk shipments.

NSFPA members understand the concerns and wishes of the American people to guard against acts of bioterrorism in connection with the food supply. We respectfully submit our comments and suggestions with a view to reducing that risk, while at the same time making sure that regulatory control measures and precautions do not cripple trade and harm the economies of our two nations.

Yours truly,

Richard D. Morrow

Richard D. Morrow
Executive Director